

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Robin Robinson <i>et al.</i>)	
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Serial No.: 10/617,569)	Confirmation No.: 5752
)	
Filed: July 11, 2003)	Group Art Unit: 1648
)	
For: Functional Influenza Virus-Like Particles (VLPS))	Examiner: Myron G. Hill
)	

DECLARATION OF GAYLE SMITH, PH.D. UNDER 37 C.F.R. § 1.132

I, Dr. Gale Smith, hereby declare as follows:

1. I am currently employed as Vice-President of Vaccine Development at Novavax, Inc. I received my Ph.D. in 1983 from Texas A & M University. Prior to Joining Novavax, I was Chief Scientific Officer for Protein Sciences Corporation and was a Research Scientist at Texas A & M University. My resume is attached.

2. The following experiments were carried out under my direct supervision:

3. Seasonal and avian influenza M1 and HA proteins were cloned and expressed in a baculovirus expression system. The seasonal influenza strains used for these experiments were A/Fujian/411/2002 and A/Wisconsin/67/2005 and the avian influenza strain used was A/Indonesia/5/05.

4. Cells expressing either seasonal M1 and HA, avian M1 and HA or a combination of seasonal and avian M1 and HA were grown under conditions that allow formation of VLPs.

5. The VLPs were harvested and isolated from the supernatant by centrifugation and by a discontinuous sucrose step gradient. The fraction comprising the VLPs was collected from the top of the gradient.
6. The VLPs isolated from the sucrose gradient were analyzed by SDS-PAGE and western immunoblot. These data are on illustrated on Exhibits 1 and 2.
7. Exhibit 1 is a stained SDS-PAGE gel. The lanes in the gel comprise the following: 1 to 5, A/Fujian M1 (seasonal) with 4 different HAs or alone; 6 to 10, A/Indo/ M1 (avian) with 4 different HAs or alone; 11 to 14, various controls.
8. Comparing the bands on the gel, the lanes that comprise VLPs comprising avian M1 have stronger bands of M1 and HA in the same lanes, while the lanes that comprise seasonal influenza have weaker bands in the gel. M1 and HA bands in the same lane is indicative of HA associating with M1. This association is indicative of VLP formation comprising M1 and HA. These data provide evidence that avian influenza M1 form VLPs more efficiently than seasonal influenza M1, with either homologous or heterologous envelope proteins. These data also show that M1 from avian influenza is strongly expressed and stable when compared to seasonal influenza M1.
9. Exhibit 2 is a western blot showing M1 expression. This blot shows that avian influenza M1 is strongly expressed as compared to seasonal M1. The intensity of the bands indicate that there is more avian M1, and thus, more VLPs.

10. I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

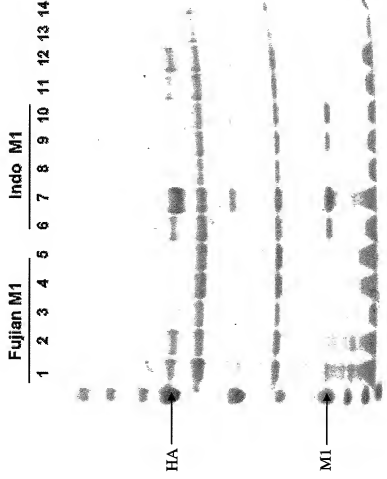
Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gale Smith", is written over a horizontal line.

Gale Smith, Ph.D.

12/3/2007
Date

EXHIBIT 1



1. 245/230 VLP H3 Fujian HANAM1 +Fuj M1
2. 384/230 VLP H3 Wisc HA + Fuj M1
3. 281/230 VLP H1 NC HA + Fuj M1
4. 301/230 VLP H5 Indo HA + Fuj M1
5. 230 VLP Fuj M1
6. 245/299 VLP H3 Fujian HANAM1 + Indo M1
7. 384/299 VLP H3 Wisc HA + Indo M1
8. 281/299 VLP H1 NC HA + Indo M1
9. 301/299 VLP H5 Indo HA + Indo M1
10. 299 VLP Indo M1
11. 245 VLP H3 Fujian HANAM1
12. 384 H3 Wisc HA
13. 281 H1 NC HA
14. 301 H5 Indo HA

EXHIBIT 2

